

ANNUAL BURDEN FOR RECORD KEEPERS—Continued

Information collection title	Annual number of record keepers	Annual number of responses per record keeper	Average burden hours per response	Annual total burden hours
Sponsor Verification Application (Form SVP-3/3s)—Cases requiring a Financial Care Plan	216	87	1.00	
Sponsor Verification Application (Form SVP-3/3s)—Applicants choosing to submit to an ORR-paid DNA test	216	78	1.00	
Sponsor Care Agreement (SVP-4/4s) All UAC check-in	216	265	0.75	42,930
Sponsor Care Agreement (SVP-4/4s) All UAC check-in	11	5,200	3.00	171,600
Fingerprinting Instructions (SVP-7/7s)	216	177	1.00	38,232
Letter of Designation for Care of a Minor (Form SVP-9/9s)	216	79	0.50	8,532
Estimated Annual Burden Hours Total				714,246

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores v. Reno Settlement Agreement*, No. CV85-4544-RJK (C.D. Cal. 1996).

Mary B. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Information Collection Request for the State Grants for Assistive Technology Program Annual Progress Report; OMB #0985-0042

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget

(OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to the reinstatement with change for the information collection requirements related to State Grants for Assistive Technology Program Annual Progress Report [OMB #0985-0042].

DATES: Submit written comments on the collection of information by February 4, 2021.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find the information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Robert Groenendaal, Assistive Technology Program Manager, Center for Innovation and Partnership in the Office of Interagency Innovation Administration for Community Living; Email: Robert.Groenendaal@acl.hhs.gov; Phone: 202-795-7356.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

The Administration for Community Living (ACL) is requesting approval for a reinstatement with change for the information collection associated with the State Grants for Assistive Technology Program Annual Progress Report (AT APR) 0985-0042.

The information collected through this data collection instrument is

necessary for ACL and states to comply with Sections 4 and 7 of the Assistive Technology Act of 1998, as amended (AT Act). ACL is requesting a reinstatement with change of a previously approved information collection under OMB No. 0985-0042.

Section 4 of the AT Act authorizes grants to public agencies in the 50 states and the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Marianas (states and outlying areas). With these funds, the 56 states and outlying areas operate "Statewide AT Programs" that conduct activities to increase access to and acquisition of assistive technology (AT) for individuals with disabilities and older Americans. Divided into two comprehensive activity categories: "State-level Activities" and "State Leadership Activities." According to Section 4 of the AT Act, as a condition of receiving a grant to support their Statewide AT Programs, the 56 states and outlying areas must provide to ACL: (1) Applications and (2) annual progress reports on their activities.

Applications: The application required of states and outlying areas is a three-year State Plan for Assistive Technology (State Plan for AT or State Plan) (OMB No. 0985-0048). The content of the State Plan for AT is based on the requirements in Section 4(d) of the AT Act. As a part of this State Plan, Section 4(d)(3) of the AT Act requires that states and outlying areas set measurable goals for addressing the assistive technology needs of individuals with disabilities in education, employment, community living and information technology/telecommunications.

Every state and outlying area is required to include a minimum of seven prescribed measurable goals in its State Plan. These seven goals apply to all

states and outlying areas in order to aggregate information on performance of the program at the national level. National aggregation of data related to these goals is necessary for the Government Performance and Results Modernization Act of 2010 (GPRAMA) (Pub. L. 111–352), as well as an Annual Report to Congress (see “Section 7 Requirements Necessitating Collection” below).

Therefore, this data collection instrument provides a way for all 56 grantees—50 U.S. states, DC, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands to collect and report data on their performance in a consistent manner, including a uniform survey to be given to consumers. This uniform survey is included as part of the data collection package.

Annual Reports: In addition to submitting a State Plan every three years, states and outlying areas are required to submit annual progress reports on their activities. The data required in that progress report is specified in Section 4(f) of the AT Act.

Section 7(d) of the AT Act requires that ACL submit to Congress an annual report on the activities conducted under the Act and an analysis of the progress of the states and outlying areas in meeting their measurable goals.

This report must include a compilation and summary of the data collected under Section 4(f). In order to make this possible, states and outlying areas must provide their data uniformly. This data collection instrument was developed to ensure that all 56 states and outlying areas report data in a consistent manner in alignment with the requirements of Section 4(f).

As stated above, ACL will use the information collected via this instrument to:

- (1) Complete the annual report to Congress required by the AT Act;
- (2) Comply with reporting requirements under the Government Performance and Results Modernization Act of 2010 (GPRAMA) (Pub. L. 111–352); and
- (3) Assess the progress of states and outlying areas regarding measurable goals in their State Plans for AT.

Data collected from the grantees will provide a national description of activities funded under the AT Act to increase the access to and acquisition of AT devices and services through statewide AT programs for individuals with disabilities. Data collected from grantees will also provide information for usage by Congress, the Department, and the public. In addition, ACL will

use this data to inform program management, monitoring, and technical assistance efforts. While States will be able to use the data for internal management and program improvement.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** on September 28, 2020 in 85 FR 60803. There were 32 public comments received during the 60-day FRN comment period.

Proposed change in State Financing Activities: Financial Loan—partnership loans reported with no guarantee or interest buy-down have narrative description added to document subsidy/investment.

Comment Summary: Two State AT Act Program grantees commented in support. One organization representing the State AT Act Programs requested clarification.

ACL Response: Sentence identified as confusing has been deleted in the AT APR—IC document.

Proposed change in Reuse: Exchange—option for automatic exclusion of exchange recipients from performance measure data collection eliminated.

Comment Summary: Two AT grantees commented in support. One AT organization requested clarification.

ACL Response: Clarification text has been added into the AT APR—IC document.

Proposed change in Device Loan— separate type of borrower and type of device data reporting tables by purposed of loan.

Comment Summary: Three AT grantees commented in support. One requested clarification of timeline for implementation.

ACL Response: No changes made. ACL will clarify the timeline for implementation to begin with federal fiscal year 2022, with first data collection October 1, 2021 to provide time for data system revision.

Proposed change in Device Demonstration— separate decision-making participant from other participants reported in participant type table.

Comment Summary: Three AT grantees commented in support. One grantee and one organization commented in opposition with one saying this is duplicative data reporting and one saying it is understood that an individual with a disability is the decision-maker unless unable to be and then it is the caregiver/provider role. One grantee requested clarification of the timeline for implementation.

ACL Response: The proposed change is designed to support data fidelity by ensuring the decision-maker is identified by type within what can be a larger number of participants reported for each demonstration event. Currently all participants are reported by type. As a result, this change does not duplicate or increase data reporting burden. It only separates the decision-maker participant type reported from the type or types reported for all other participants. No change is made. ACL will clarify the timeline for implementation to begin with federal fiscal year 2022, with first data collection October 1, 2021 to provide time for data system revision.

Updated Outcome Measures— Overall acquisition and access performance measure tables and consumer satisfaction tables updated to align with outcome/output data and targets used by ACL for program evaluation and budget justification since FY18.

Comment Summary: One AT organization requested clarification.

ACL Response: Clarification has been added to the AT APR—IC document.

Proposed new data elements in Public Awareness and Information & Assistance— New question added for description of partnerships as part of public awareness, new data table added to report how individuals learned about the AT Program, new information request in Notes for description of partnerships that increase referrals.

Comment Summary: Five AT grantees and one AT organization commented in opposition to these changes and the new data element. All commenters expressed concern about lack of clarity and significant new data burden (both for AT Programs and consumers) associated with the proposed new data collection requirements.

Commenters suggested these new data elements be removed and requested ACL work with AT Act grantees to determine the most efficient and effective way to report referral source data in a future information collection.

ACL Response: ACL is appreciative of the participation of AT stakeholders in the **Federal Register** Notice comment process and values the submission of comments on the proposed updates to the Public Awareness and Information and Assistance sections of the AT APR data collection instrument. Once approved, ACL intends to address and work through these changes with AT stakeholders to identify the most efficient and effective way to collect referral source data in the Information Collection.

State Improvement Outcomes— new optional section added to collect data on

coordination and collaboration with two new required narratives and associated drop-down menu data.

Comment Summary: Two AT grantees commented in support.

ACL Response: No changes made.

Leveraged Funding—eliminated Section B and folded data into Section A to simplify.

Comment Summary: Two AT grantees commented in support.

ACL Response: No changes made.

Instruction Manual—deleted redundant text and updated AT Taxonomy.

Comment Summary: Two AT grantees commented in support.

ACL Response: No changes made.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows:

(A) A web-based system that collects data from states.

(B) A performance measurement survey that states collect from individuals

(C) A customer satisfaction survey that states collect from individuals.

(A) Fifty-six grantees report to ACL using the *web-based data collection system*. A workgroup of grantees estimated that the average amount of time required to complete all responses to the data collection instrument is 80 hours annually. The estimated response burden includes time to review the instructions, gather existing data, and complete and review the data entries. These estimates are based on the experience of staff who implement these programs at the state level. In addition, we project that clean-up and clarification of data elements will

require no change in data burden estimates.

(B) The fifty-six grantees ask consumers to complete surveys that provide information on their performance related to the state’s *measurable goals*. Historical data from states indicates that the average state will ask for this information from 3,242 consumers at 1 minute per consumer to complete the question survey, for a total of 54 hours annually.

(C) The fifty-six grantees also ask consumers to complete *customer satisfaction surveys*. Historical data from states indicated that the average state asks for this information from 3,242 consumers at 1 minute per consumer, for a total of 54 hours annually.

	Number of responses	Hours per response	Annual burden per grantee	Total annual burden hours
Work-Based System	56	1.428	80	4,480
Performance Measurement	3,242	0.01666	54	3,024
Customer Satisfaction	3,242	0.01666	54	3,024
Subtotal			188	10,528
Program Support	56	4	208	11,648
Record Keeping Burden	56	0.14286	8	448
Subtotal			216	12,096
Total			404	22,624

Dated: December 29, 2020.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-2105]

Mouse Embryo Assay for Assisted Reproduction Technology Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Mouse Embryo Assay for Assisted Reproduction Technology Devices.” This guidance document provides recommendations

on conducting the mouse embryo assay to support premarket submissions and lot release of assisted reproduction technology devices.

DATES: The announcement of the guidance is published in the **Federal Register** on January 5, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”